Comments
Report on Carcinogens Review Process

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November 29, 2011

These comments are based on approximately 30 years professional experience with risk assessment and carcinogen classification. I have served on the National Academy of Sciences Committee on Institutional Risk Assessment (1983), the NTP Board of Scientific Counselors and its Subcommittee to Review the Report on Carcinogens, and two working groups which completed IARC Monographs. I was a voting member of the BSC group which recommended the existing listing criteria. These comments are my own, and are not sponsored by any industry, NGO, government agency or previous advisory group.

The process for development and review of the ROC has been modified several times.

1. The existing process for developing the ROC is more than sufficiently transparent to the public, has more than sufficient opportunities for public input and comment, and is intensively and more than sufficiently scientifically reviewed.

2. However, the practice of the office of the Secretary of Health and Human Services in approving the ROC before publication is opaque.

3. The proposed new process streamlines the ROC development process and is superior to and more flexible than the existing process. The existing process relies on ad hoc panels of experts for each substance to recommend a classification. The panels of experts used in the current process were qualified and equivalent to any peer review panel which might be employed by the NTP. However, it is more efficient for the NTP to generate a proposed listing, with rationale, which would then be submitted to scientific review.

4. Specifying that the NTP Board of Scientific Counselors be the unique peer review group for ROC listing is less than optimal. The distribution of expertise in the BSC may not match with the scientific controversies associated with a particular substance, especially with regard to studies in people. Review of multiple substances by the BSC may overload the time available to BSC members. This comment is based on personal experience as a member of a

BSC subcommittee which reviewed ROC listings in a process used before the current process.

5. The classification terminology for carcinogens – “Known” and “Reasonably Anticipated” - used in the ROC are defined by statute. There are at least 8 additional sets of authoritative terminology for classification of carcinogens (IARC, OSHA cancer policy, NIOSH, EPA, ATSDR-CDC, California Proposition 65, Globally Harmonized System, ACGIH.) The approach taken by NTP is consistent with the statute, although less inclusive than several other classification schemes.

6. The criteria for evaluation of data from people (epidemiology) employed for the ROC are essentially identical to those employed by IARC, the longest standing and most authoritative source of classifications, and other authoritative bodies and agencies.

7. The criteria for evaluation of substances based on laboratory evidence employed by the Report on Carcinogens are somewhat less inclusive than those employed by the International Agency for Research on Cancer. Laboratory results for which IARC would determine there is sufficient evidence for carcinogenicity might be classified as limited evidence for carcinogenicity according to the IARC criteria. Therefore, a substance classified as a carcinogen based on laboratory evidence by IARC might not be listed by the ROC.

8. It is essential that financial conflict of interest requirements be maintained for scientific review groups in the ROC process. Representatives of potentially impacted economic interests already have plenty of voice through public comments.

9. It is essential that federal employees be permitted to participate in scientific review groups for the ROC process.